

CHARGE: 501(b)—the strength of the article, while held for sale, differed from the standard for digitoxin tablets set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin.

DISPOSITION: 9-19-57. Default—destruction.

5492. Rythrogen. (F.D.C. No. 40398. S. No. 53-744 M.)

QUANTITY: 93 10-cc. vials at Dallas, Tex.

SHIPPED: 4-4-57 and 6-13-57, from Saratoga Springs, N.Y., by G. F. Harvey Co.

RESULTS OF INVESTIGATION: Examination showed that the article contained less than the declared amount of thiamine hydrochloride.

LIBELED: 8-1-57, N. Dist. Tex.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it was represented to possess, namely, 4.5 mg. per cubic centimeter of thiamine hydrochloride; and 502(a)—the label statement "Each cc Contains * * * Thiamine Hydrochloride 4.5 mg." was false and misleading.

DISPOSITION: 9-3-57. Default—destruction.

5493. Pep-Ti-Kon. (F.D.C. No. 40410. S. No. 44-189 M.)

QUANTITY: 96 8-oz. btls. at Forrest City, Ark.

SHIPPED: 5-2-57, from Memphis, Tenn., by Berjon Co.

LABEL IN PART: "Blood-building Tonic * * * Pep-Ti-Kon."

RESULTS OF INVESTIGATION: Examination showed that the article contained 65 percent of the labeled amount of riboflavin.

LIBELED: 8-9-57, E. Dist. Ark.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it was represented to possess, namely, 3.0 mg. per fluid ounce; and 502(a)—the label statement "Each fluid ounce provides: * * * vitamin B₂ (Riboflavin) 3.0 Mg." was false and misleading.

DISPOSITION: 9-11-57. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

5494. Nulsar. (Inj. No. 309.)

COMPLAINT FOR INJUNCTION FILED: 4-25-57, E. Dist. Mich., against Appleton Drugs, Inc., and Appleton Drug Laboratories, Inc., of Detroit, Mich., and Samuel Krone, president of the corporations and owner of the businesses operated under the names of Appleton Drugs and Nulsar Drug Laboratories, at Detroit, Mich.

LABEL IN PART: (Ctn.) "Nulsar-6 Special Tablets * * * For each full ounce of the enclosed product, the following ingredients are included: Powdered extracts of cattle organs in the following manner: Brain substance 2 grains Suprarenal substance ½ grain Desiccated liver 20 grains Hemoglobin 5 grains Gastric mucin 4 grains also: Ferrous gluconate 1 grain Pure dehydrated cream and milk containing not less than 53% up to 60% milk fat at the time of manufacture 325 grains Powdered cocoa, flavoring, sucrose, preservative, added."

*See also Nos. 5481, 5482, 5484, 5485, 5487-5489, 5492, 5493.

ACCOMPANYING LABELING: Leaflet headed "THE 'NULSAR-6' STORY To You—With an Ulcer problem—Here is wonderful news"; two sheets consisting of a reprint of a portion of an article published in the July 1956 issue of Confidential Magazine and headed "The end of 20,000,000 American bellyaches * * * an amazing new pill that banishes ulcers without drugs or surgery!" and a sheet headed "Nulsar Drug Laboratories, 18444 Sorrento Avenue, Detroit 35, Michigan—Dear Doctor: You have probably seen the enclosed publicity given to the imported tablets that are being taken for ulcers."

CHARGE: The complaint alleged that the defendants were violating the Act by causing the introduction and delivery for introduction into interstate commerce of the drug *Nulsar* which was misbranded as follows:

502(a)—the labeling of the article, including the designation "Nulsar," the statement "'Nulsar-6' Tablets are most helpful in stomach and duodenum conditions that need a highly absorbent coating over any painful lesions or areas," appearing on the carton, and the statements in the accompanying labeling, were false and misleading since such labeling, when viewed in the setting in which used, represented and suggested that the article was adequate and effective in the treatment of ulcers in humans and in the treatment of stomach and duodenum conditions that need a highly absorbent coating over painful lesions and areas, whereas the article was not adequate and effective in the treatment of such conditions.

The complaint alleged also that if the defendants were forced by an injunction to refrain from using the above-mentioned labeling on interstate shipments of the article, the defendants would not discontinue interstate distribution of the article but would, unless enjoined, continue to ship the article in interstate commerce without labeling stating the conditions and purposes for which the article was intended; and that in such case, the article would be misbranded under 502(f) (1) in that its labeling would fail to bear adequate directions for use, because of the omission from the labeling of statements of the conditions and purposes for which the article was intended.

DISPOSITION: On 4-26-57, a temporary restraining order was issued against the defendants. On 5-14-57, the defendants having consented, a decree of permanent injunction was entered enjoining the defendants against using the names, "Nulsar," "'Nulsar-6'" "Nulsar Drug Laboratories," or "Nulsar Products Company," in any capacity in interstate commerce, and against introducing and delivering for introduction into interstate commerce the article of drug designated as "Nulsar," and against causing the introduction or delivery for introduction into interstate commerce of *Nulsar* or any article of similar composition which—

(1) is accompanied by the above-mentioned accompanying labeling, or any written, printed, or graphic matter substantially to the same effect;

(2) bears or is accompanied by written, printed, or graphic matter which suggests use of the article in the treatment of ulcers, or which contains the false and misleading representations referred to above, or which is otherwise false and misleading; or

(3) does not have labeling that clearly states every disease, condition, symptom, and purpose for which the article is intended to be used and for which it is represented by any means to the public.

5495. Smylax tablets, Smylax tonic, and Ardine tablets. (Inj. No. 313.)

COMPLAINT FOR INJUNCTION FILED: 6-25-57, N. Dist. Ill., against Alexander P. McArthur, t/a Smylax Co. and Ardine Co., Chicago, Ill.

ACCOMPANYING LABELING: (Smylax tablets and Smylax tonic) Leaflets entitled "Smylax Tonic Good For Many Ailments * * * Why Grow Old? Be Ageless—Defeat Time Forget The Calendar" and "A Hidden Secret Disclosed"; (Ardine tablets) leaflets entitled "Ardine For Feminine Hygiene and Health" and "Ardine For Ideal Feminine Hygiene and Health" and a booklet entitled "Ardine * * * A Boon To Happy Womanhood."

CHARGE: The complaint alleged that the defendant was engaged in the business of distributing and selling *Ardine tablets*, consisting of chloramine T, starch, and sodium bicarbonate; *Smylax tablets*, consisting of an extract of sarsaparilla root and powdered licorice; and *Smylax tonic*, consisting of sarsaparilla extract and flavoring in a simple sirup; and, further, that the defendant had been causing the introduction and delivery for introduction into interstate commerce of such articles which were misbranded as follows:

Smylax tablets and *Smylax tonic*. 502(a)—the labeling of the articles contained false and misleading representations that the articles were adequate and effective treatments for retarding old age; overcoming the lack of hormones in the body; enabling one to keep alive and healthy for a longer life; feeding the glands; overcoming emotional, physical, sexual, and mental difficulties; overcoming a condition of tired muscles, starving nerves, impaired blood circulation, and low resistance to infection; providing vitality; overcoming skin eruptions, general debility, muscle cramps, infections, poisons, head pains, sinus infection, a condition of poisoned blood stream, skin disease, chronic rheumatism, and scrofula; providing a gland food to enable the glands to produce testosterone, progesterone, and cortisone; overcoming angina pectoris, ringworm, psoriasis, and other skin ailments, arthritis, rheumatic fever, prostate gland weakness, menstrual difficulties, menopausal difficulties, nervous headaches, hot flashes, menstrual cramps, emotional upsets, depression, and allergic difficulties; preventing softening of the bones, diabetes, high blood pressure, and heart attacks; and providing good health.

Ardine tablets. 502(a)—the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for providing good health and happiness; enabling one to retain youth, beauty, and vigor; providing a complete germicidal power that will kill all germs and bacteria and remain effective for such purposes for several hours when placed in the vagina; preventing infection, including gonorrhea; and overcoming pyorrhea, ringworm, eczema, and leucorrhea.

DISPOSITION: On 6-28-57, after a hearing at which the defendant appeared, the court entered a preliminary injunction. On 8-8-57, the defendant having failed to answer or otherwise plead to the complaint, a default decree of permanent injunction was entered against the defendant enjoining him against commission of the acts complained of.

5496. Diaplex. (F.D.C. No. 40349. S. No. 72-982 M.)

QUANTITY: 20 12-oz. ctns. at Salt Lake City, Utah.

SHIPPED: 1-18-57, from Canyon City, Colo., by H. W. Pierce.

LABEL IN PART: (Ctn.) "DIAPLEX * * * contains as follows: Calcium Fluoride Calcium Sulfate Calcium Phosphate Iron Phosphate Potassium Chloride Silica Sodium Chloride Iodine Sulphur Pure Phosphate Pure Calcium Boron Protein All these organic minerals were found in this herb. Diaplex: Vitamin Content A, B, B₁, C, D, and traces of others including many valuable minerals naturally compounded * * * Mile Hi Food Co., Denver 11, Colorado."